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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LI, QIAN JANICE	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,835	CHANCELLOR ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,38-41,43-45 and 64-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,38-41,43-45 and 64-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5/02 10/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The amendment and response filed 11/3/04 have been entered. Claims 22, 38, 40, 41, 43-45 have been amended. Claims 1-21, 23-37, 42, 46-63 have been cancelled. Claims 64-92 are newly submitted. Claims 22, 38-41, 43-45, 64-92 are under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in 11/3/04 response would be addressed to the extent that they apply to current rejection.

Claim Objection

Claim 41 is objected to because the newly added portion of the claim starting with "and reduction..." is drawn to a process of alleviation of an immune response, the phrase fails to further define the preparation. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejection of Claims 21, 22, 38-63 under 35 U.S.C. 112, first paragraph, is withdrawn in view of claim amendment and response.

Claims 82 and 83 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making a three-dimensional scaffolding graft composition comprising muscle-derived stem cells (MDSC) and a matrix material which forms a 3-D muscle tissue, does not reasonably provide enablement for making a two-dimensional muscle tissue, and it does not reasonably provide enablement for a graft composition comprising MDSC and a matrix material that forms *any* organ structure beyond muscle and connective tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention are summarized in *In re Wands*, (858 F2d 731, 737, 8 USPQ 2d 1400, 1404, (Fed Cir.1988)). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided. The factors most relevant to this rejection are the scope of the claims relative to the state of the art and the levels of the skilled in the art, and whether sufficient amount of direction or guidance are provided in the specification to enable one of skill in the art to practice the claimed invention.

Given the broadest reasonable interpretation, claim 82 encompasses making a two-dimensional muscle tissue and any organ structure. However, since a cell itself is a three-dimensional object, when combined with matrix materials, it would still be at least

three-dimensional. The specification is silent with respect to how to use a 3-D cell to make a 2-D tissue, thus, fails to provide sufficient guidance for what is now claimed.

Given the broadest reasonable interpretation, claims 82 and 83 encompass using muscle-derived stem cells (MDSC) and a matrix material to make any organ structure in addition to a muscle tissue. However, as indicated in pages 6-7 of the previous office action, neither the art of record nor the specification discloses that MDSCs could differentiate to other cell types (such as liver, lung, and blood cells) other than muscle and connective tissue. Assuming the MDSC does have the potential to differentiate to all types of body cells, the specification fails to teach how to induce the MDS differentiate to only the cell type of interest. Thus, the specification fails to provide an enabling disclosure to support the full scope of the claims.

Accordingly, based upon the limited disclosure, the underdeveloped state of the art, the level of the skill, and the breadth of the claims, one skill in the art would have been required to perform undue experimentation to practice the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 41, 65-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 is vague and indefinite because the phrase "and reduction...". Claim 41 is drawn to a preparation comprising MDSCs, whereas the phrase is drawn to a process

of treating immune rejection. It is unclear what the applicants intend to claim, a product or a method, thus, the metes and bounds of the claims are uncertain. Moreover, the subject of the immune response is missing in the phrase, and thus the metes and bounds of the claims are unclear.

Claims 22, 65-92 are vague and indefinite because of the claim recitation, "about". Since the upper and lower limit (range) of "about" is unclear, and thus the metes and bounds of these claims are uncertain.

Claim 65 is vague and indefinite because of the claim recitation "12 hours prior to use". It is unclear what type of use the claim encompasses, "use" them for continued culture or for implantation, and thus the metes and bounds of the claim are uncertain. For example, if it is a use for co-culture, then any MDSC and matrix co-culture for longer than 12 hours would meet claim limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

The previous provisional rejection of Claims 21, 22, 38, 40-44, 46-56, 61 under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/549,937, is withdrawn because Claim 115 in the cited application has been canceled.

The previous provisional rejection of Claims 21, 22, 38, 40-44, 46-56, 61 are rejected under 35 U.S.C. 102(f) is withdrawn because Claim 115 in the cited application has been canceled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 38-41, 43-45, 64 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Ye et al* (Eur J Cardio-Thorac Surg 2000 April;17:449-54), or *Vandenburgh* (US 6,503,504), in view of *McDowell et al* (US 6,171,340), and *WO*

99/56785, and as evidenced by *Capelli et al* (US 5,045,601) and *Humes et al* (US 2002/0090389).

Applicants argued what is lacking for each cited reference, and go on to argue that prior to Applicants' discovery, the preparation of cell matrix materials required long time period to grow and engineer tissues or matrices for implantation which cause routine delays whereas in the present invention, MDSCs are incubated with the matrix material in vitro for less than about 12 hours prior to use.

In response, it is noted that these rejected claims do not require incubation time prior to administration. Moreover, applicants are reminded that these claims are drawn a preparation comprising MDSCs and a biomatrix, thus as long as the prior art preparation contains the two elements, it meets claim limitation.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, *Ye et al* or *Vandenburgh or WO 99/56785* are cited for disclosing a scaffolding preparation comprising MDSC and a biomatrix, wherein the only element differs from instant claims is the elected species of the type of biomatrix, SIS. *McDowell et al* is cited for establishing that it is known in the art to use SIS as the biomatrix in addition to the biomatrix used in the *Ye et al* or *Vandenburgh; Vandenburgh* and *WO 99/56785* are cited for the well known characteristics of the contractibility of

MDSCs, and proper numbers of cells that should be seeded in the biomatrix. It is the combined teachings that are obvious over the claimed invention.

Concerning each of the cited references, Applicants first argue that *Ye et al* teaches away from using a biomatrix. In response, indeed, *Ye et al* stated in the abstract that they developed a new method for making a completely autologous 3-D tissue graft without using [allogenic] scaffolding materials. But this does not negate the presence of autologous biomatrix materials in their 3-D tissue comprising MDSCs and autologous matrix and using such for cardiovascular surgery. *Ye et al* teach that because of the concern of immune rejection of the allogenic scaffolding matrix material, they substitute such with the matrix material secreted by the autologous MDSCs. They teach after four weeks of culture, the multi-layered muscle cells are surrounded by extracellular matrices (e.g. abstract and fig. 5). Thus, the graft material taught by *Ye et al* meets basic requirement of claim limitation except the SIS.

Applicants go on to argue that *Vandenburgh* teaches away from MDSCs because at least 50% of the cells containing a foreign DNA are non-proliferative. In response, cells containing a foreign DNA do not inherently non-proliferative. In fact, *Vandenburgh* teaches explicitly that expressing a foreign DNA does not impair the ability of the MDSCs to proliferate and differentiate (column 22, lines 9-13). Even if they are, claims as written does not exclude the presence of non-proliferative cells, and at least another 50% cells are MDSCs. Although *Vandenburgh* teaches a means of eliminating proliferating cells in the produced graft, this is only an optional embodiment. In the working examples, this means was not included (e.g. section 3, columns 21-22).

Thus, plenty of MDSCs are present in the cultured graft materials, and the preparation taught by *Vandenburgh* still meets claim limitation except for the specific teaching of SIS. On the other hand, applicants fail to disclose in the specification that after 12-hr incubation, how many MDSCs remain to be undifferentiated.

Applicants then argue that *McDowell et al* do not make up for the many deficiencies in the above-cited references. In response, *McDowell et al* teach a composition for repairing damaged joint comprising stem cells (column 6, line 22) and a substrate (biomatrix) that may enhance tissue growth (column 6, lines 45-62) or serve as an anchor and scaffold to which the cells attach. Accordingly, *McDowell et al* supplemented the teaching of above cited references by establishing that it is well known in the art that SIS could be used as a biomatrix scaffolding.

Applicants then argue that WO99/56785 does not teach combining the MDSCs with a biomatrix. In response, this was taught by *Vandenburgh* and *Ye et al.*

Finally, the '602 patent and '389 patent are cited as evidence to establish that the bio-adhesive such as fibrin gel is well known in the art for attaching cells for implant.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Ye et al, or Vandenburgh*, by simply using muscle stem cells as the type of stem cells as taught by or *WO 99/56785*, and SIS as the type of substrate as taught by *McDowell et al* to make a tissue repair composition with a reasonable expectation of success. Given the types of stem cells known in the art, and the type of biocompatible matrix materials known in the art, these limitations would fall within the bound of optimization. Given the success

taught by each of the cited references in making and using a 3-D scaffolding graft, the skilled artisan would have reasonable expectation of success of making a preparation comprising MDSCs and a SIS matrix.

Thus, for reasons of record and those set forth *supra*, the rejection stands.

The prior rejection of Claims 21, 22, 46-56, 59-61 under 35 U.S.C. 103(a) as being unpatentable over *WO 99/56785,* in view of *Kropp et al* (J Urol 1996;155:2098-2104), *Vandenburgh* (US 6,503,504), and *McDowell et al* (US 6,171,340), is withdrawn because the claims 21, 46-56, 59-61 have been canceled and claim 22 is now depend on the newly submitted claims.

Claims 22, 65-92 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over *Vandenburgh* (US 6,503,504), in view of *McDowell et al* (US 6,171,340), and *Young et al* (J Orthop Res 1998;16:406-13), and as evidenced by *WO 99/56785* and *Kropp et al* (J Urol 1996;155:2098-2104),

The newly submitted claims are drawn to a composition comprising MDSCs and a biomatrix material admixed in vitro for less than about 12 hours prior to use.

Vandenburgh teaches a composition comprising muscle stem cells (e.g. fig. 2) in an extracellular matrix suspension (e.g. abstract), and a vessel (3-D scaffolding biomatrix) having a three dimensional geometry (fig. 1), wherein the muscle stem cells are attached to the outer surface of the vessel having attachment surfaces (e.g. column 3, lines 11-19), and an implantable three-dimensional scaffolding would form simulating

the *in vivo* tissue morphology (e.g. abstract) and having muscle contractility and could be used for tissue repair (e.g. fig 8), wherein the MDSCs were seeded 1-4x10^6 cells per vessel (column 10, line 52), and wherein the MDSCs were isolated from skeletal muscle (e.g. column 22, § G). Although *Vandenburgh* does not teach admix the two components without further culture or limiting the culture to less than 12 hours, he does teach the muscle stem cells could be directly administered to a patient in need without the biomatrix (e.g. fig. 7). *Vandenburgh* does not teach using SIS as the matrix in the preparation.

McDowell et al supplemented the teach of *Vandenburgh* by establishing that it is well known in the art stem cells could be just attached or inserted into the matrix without co-culture, and SIS is a well known matrix material for making a 3-D cell graft. *McDowell et al* teach a composition for repairing damaged joint comprising stem cells (column 6, line 22) and a substrate that may enhance tissue growth (column 6, lines 45-62), wherein the substrate could be SIS (a polymer derived from small intestinal submucosa). *McDowell et al* teach that stem cells could be administered directly to the surface of the bone wound, as a gel or sponge construct, or the stem cells may be attached to shield or spacer before implantation (admix), wherein the shield and spacer serve as an anchor or scaffold to which the cells attach (column 6, lines 21-26), or the cells for transplant may be inserted into the substrate material (column 6, lines 61-62). *McDowell et al* also teach the bio-adhesive material such as fibrin glue (column 6, line 36). Although *McDowell et al* do not teach specifically the MDSCs, such has been taught by *Vandenburgh*. Although not relied upon, *WO 99/56785* is devoted to MDSCs

and its healing effect when administered *in vivo* without a matrix, wherein the MDSCs are directly injected into urethral wall for treating urinary stress incontinence (example 2), and the detrusor contractility (the major contractile muscle of the bladder) was improved (example 3). The MDSCs were also injected to joints and bone tissue for repair, which evidenced the well-known status of MDSCs in the art. Although not relied upon, *Kropp et al* use SIS as a scaffold for regenerative surgery of urinary bladder, and concluded that it is an option for bladder reconstruction. The teaching of *Kropp et al* evidenced that it is well known in the art that in the absence of any stem cells, the SIS alone could repair the damaged connective tissue.

Similar to the teaching of *McDowell et al*, *Young et al* teach a composition comprising the mesenchymal stem cells (also called noncommitted progenitor cells of musculoskeletal tissue) and a resorbable 3-D collagen matrix, which form a stem cell biomatrix almost in no time (e.g. mid-section of column 2, page 407). After 40 hours co-incubation, the biomatrix contracted to about 30% of the original size. *Young et al* teach (1st paragraph, page 406), "THESE RESORBABLE DEVICES WERE DESIGNED TO PROVIDE AN INITIAL LOAD-BEARING STRUCTURE TO SERVE AS A SCAFFOLD FOR BOTH THE CELLS INTRODUCED INTO THE DEFECT SITE AND THOSE RECRUITED TO THE AREA". When applied to a wound model, the stem cell-biomatrix significantly improves tendon repair compared with a contra-lateral, natural repair site (e.g. results and discussion). Apparently, it is a well-established concept in the art to make a resorbable construct to promote wound healing. Although *Young et al* did not use the MDSCs and incubated the construct for more than 12 hrs, a reasonable success is well expected when one combines the

MDSCs and SIS for only a short period of time before implantation because these two components have been proven effective when each was used alone.

Evidently, before the instant effective filing date, *Vandenburgh*, *McDowell et al* and *Young et al* teach that in tissue repair, there are multiple approaches for transplanting the stem cells and substrate materials, they could be co-cultured or just attached together, and they could be implanted alone or in combination. They also teach the advantages of the matrix materials as an anchor for implanted and recruited cells, and for enhancing cell growth. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use either the cultured stem cell/matrix or attached stem cell/matrix with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because the matrix materials could enhance wound healing as taught by *McDowell et al* and *Young et al.* Given the numerous options for tissue repair, and levels of the skilled, one of ordinary skilled in the art would have been able to determine which approach to use depending on the clinical conditions of the patients and resources available to the artisan. Given the success as taught by *Vandenburgh*, *McDowell et al* and *Young et al*, the skilled artisan would have had a reasonable expectation of success to just admix the two components without long period of incubation.

Moreover, considering that the MDSCs or SIS *alone* could be successfully used for tissue repairing as evidenced by *WO 99/56785 and Kropp et al,* the skilled artisan would have had a reasonable expectation of success to just admix the MDSCs and SIS without more than 12 hrs co-culture. The instant situation is amenable to the type of

analysis set forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980), wherein the court held that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to produce a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Hence, it would have been *prima facie* obvious to one of ordinary skill in the art to combine the compositions of MDSCs and SIS to generate a new composition for the treatment of cancer with a reasonable expectation of success. Thus, the claimed invention as a whole was clearly *prima facie* obvious in the absence of evidence to the contrary.

Although only *Vandenburgh* discussed the number of MDSCs were seeded on each vessel, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the amount of cells should be used for tissue repair. Given the state of the art in tissue culture technology, this limitation (claims 71-73) would fall within the bounds of optimization as evidenced by WO 99/56785 (e.g. examples 3 and 7).

Although *MacDowell et al* do not specify the timing of stem cell attachment to the anchoring material, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine an appropriate time for attachment before transplantation. Given the levels of the skilled in the art of transplantation, these limitations (claims 65, 74-77) would fall within the bounds of optimization.

Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

It is noted claim 65 is a product-by-process type of claim. Case law clearly states, "[E]VEN THOUGH PRODUCT-BY-PROCESS CLAIMS ARE LIMITED BY AND DEFINED BY THE PROCESS, DETERMINATION OF PATENTABILITY IS BASED ON THE PRODUCT ITSELF. THE PATENTABILITY OF A PRODUCT DOES NOT DEPEND ON ITS METHOD OF PRODUCTION. IF THE PRODUCT IN THE PRODUCT-BY-PROCESS CLAIM IS THE SAME AS OR OBVIOUS FROM A PRODUCT OF THE PRIOR ART, THE CLAIM IS UNPATENTABLE EVEN THOUGH THE PRIOR PRODUCT WAS MADE BY A DIFFERENT PROCESS." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, the specification fails to teach the structural difference between a composition wherein the MDSCs are incubated with the matrix for less than 12 hours, and a composition wherein the MDSCs are incubated with the matrix for more than 12 hours. Thus, the Office can considered both have the same structure, and perform the same function.

Applicants are reminded the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the prior art products do not necessarily or inherently possess characteristics of claimed product, which requires factual evidence demonstrating that actual, unobvious differences exist (or that the claimed products are functionally different than those taught by the prior art) and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPBI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922, 1923 (BPAI 1989).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The prior rejection of Claims 22, 38, 40-44 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 115 of U.S. Patent No. 09549,937, is withdrawn because claim 115 of the cited application has been canceled.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Ram R. Shukla** can be reached on 571-272-0735. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

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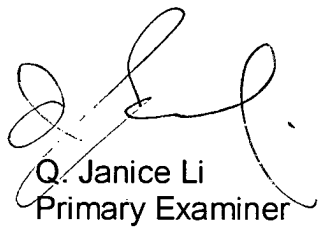

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QJL
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